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## Legislation

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<sup>(1)</sup> Text with EEA relevance

# EN

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<sup>(1)</sup> Text with EEA relevance

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2016/1675

of 14 July 2016

**supplementing Directive (EU) 2015/849 of the European Parliament and of the Council by identifying high-risk third countries with strategic deficiencies**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2015/849 of the European Parliament and of the Council of 20 May 2015 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, amending Regulation (EU) No 648/2012 of the European Parliament and of the Council, and repealing Directive 2005/60/EC of the European Parliament and of the Council and Commission Directive 2006/70/EC <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) The Union must ensure efficient protection mechanisms for the whole of the internal market, with a view to increase legal certainty for economic operators and stakeholders in general in their relationships with third-country jurisdictions. The integrity of financial markets and the proper functioning of the internal market as a whole are seriously threatened by jurisdictions with strategic deficiencies in their national anti-money-laundering and terrorism-financing frameworks. Those jurisdictions that have in place deficient legal and institutional frameworks with poor standards for controlling money flows pose significant threats to the financial system of the Union.
- (2) All Union obliged entities under Directive (EU) 2015/849 should apply enhanced due diligence measures in their relationship to natural persons or legal entities established in high-risk third countries, thereby ensuring equivalent requirements for market participants across the Union.
- (3) Article 9 of Directive (EU) 2015/849 lays down the criteria on which the Commission's assessment is to be based and empowers the Commission to identify high-risk third countries taking into account those criteria.
- (4) The identification of high-risk third countries must be based on a clear and objective assessment which focuses on a jurisdiction's compliance with the criteria laid down in Directive (EU) 2015/849 regarding its legal and institutional anti-money-laundering and countering the financing of terrorism (AML/CFT) framework, the powers and procedures of its competent authorities for the purposes of combating money laundering and terrorist financing and the effectiveness of the anti-money-laundering and countering the financing of terrorism (AML/CFT) system in addressing money laundering or terrorist financing risks of the third country.
- (5) All findings upon which the Commission's decision to include a jurisdiction in the list of high-risk third countries is to be based should be documented by robust, verifiable and up-to-date information.

<sup>(1)</sup> OJ L 141, 5.6.2015, p. 73.

- (6) It is essential that the Commission fully acknowledges relevant work already undertaken at international level for identifying high-risk third countries, in particular that of the Financial Action Task Force ('FATF'). With a view to ensuring the integrity of the global financial system, it is of the highest importance that the list of third countries laid down at Union level is closely aligned, as appropriate, with those lists agreed internationally. By promoting a global approach at international level, the Union contributes to enhancing the financial integrity worldwide and better protecting the international financial system from high-risk countries. Such a global approach serves to achieve equivalent conditions for obliged entities and avoid any disruptive effect on the international financial system.
- (7) In line with the criteria set out in Directive (EU) 2015/849, the Commission took into account all available expert assessments of factors that contribute to making a country or jurisdiction particularly vulnerable to money laundering, terrorist financing or other illicit financial activity. In particular, the Commission took into account, as appropriate, the most recent FATF Public Statement, FATF documents (Improving Global AML/CFT Compliance: ongoing process), FATF reports on International Cooperation Review, and the mutual evaluations report carried out by FATF and FATF-Style Regional Bodies in relation to the risks posed by individual third countries in line with Article 9(4) of Directive (EU) 2015/849.
- (8) Considering the high level of integration of the international financial system, the close connection of market operators, the high volume of cross-border transactions to/from the EU, as well as the degree of market opening, it is hence considered that any AML/CFT threat posed to the international financial system also represents a threat for the EU financial system.
- (9) In accordance with the latest relevant information, the Commission's analysis has concluded that Afghanistan, Bosnia and Herzegovina, Guyana, Iraq, Lao PDR, Syria, Uganda, Vanuatu and Yemen should be considered third-country jurisdictions which have strategic deficiencies in their AML/CFT regimes that pose significant threats to the financial system of the Union. Those countries have provided a written high-level political commitment to address the identified deficiencies and have developed an action plan with FATF, which would allow the requirements laid down in Directive (EU) 2015/849 to be met.
- (10) In accordance with the latest relevant information, the Commission's analysis has similarly concluded that Iran should be considered a third-country jurisdiction which has strategic deficiencies in its AML/CFT regimes that pose significant threats to the financial system of the Union. This country, identified by FATF Public Statement, has provided a high-level political commitment to address the identified deficiencies, and has decided to seek technical assistance in the implementation of the FATF Action Plan which would allow the requirements laid down in Directive (EU) 2015/849 to be met.
- (11) In accordance with the latest relevant information, the Commission's analysis has similarly concluded that the Democratic People's Republic of Korea (DPRK) should be considered third-country jurisdiction which has strategic deficiencies in its AML/CFT regime that pose significant threats to the financial system of the Union. This country, identified by FATF Public Statement, presents ongoing and substantial money-laundering and terrorist-financing risks, having repeatedly failed to address the identified deficiencies.
- (12) It is essential that the Commission extends an invitation to third-country jurisdictions identified as high-risk to fully cooperate with the Commission and international bodies with a view to agreeing and effectively implementing measures for correcting the strategic deficiencies in their anti-money laundering and terrorism financing regimes.
- (13) It is of the utmost importance that the Commission conducts a permanent monitoring of developments in the assessment of legal and institutional frameworks in place in third countries, the powers and procedures of competent authorities, and the effectiveness of their AML/CFT regimes with a view to updating the list of high-risk third countries with strategic deficiencies,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

The list of third-country jurisdictions which have strategic deficiencies in their anti-money laundering and countering the financing of terrorism regimes that pose significant threats to the financial system of the Union ('high-risk third countries') is laid down in the Annex.

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*Article 2*

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 14 July 2016.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX

**High-risk third countries**

I. High-risk third countries which have provided a written high-level political commitment to address the identified deficiencies and have developed an action plan with FATF.

No	High-risk third country
1	Afghanistan
2	Bosnia and Herzegovina
3	Guyana
4	Iraq
5	Lao PDR
6	Syria
7	Uganda
8	Vanuatu
9	Yemen

II. High-risk third countries which have provided a high-level political commitment to address the identified deficiencies, and have decided to seek technical assistance in the implementation of the FATF Action Plan, which are identified by FATF Public Statement.

No	High-risk third country
1	Iran

III. High-risk third countries which present ongoing and substantial money-laundering and terrorist-financing risks, having repeatedly failed to address the identified deficiencies and which are identified by FATF Public Statement.

No	High-risk third country
1	Democratic People's Republic of Korea (DPRK)

**COMMISSION IMPLEMENTING REGULATION (EU) 2016/1676****of 7 September 2016****entering a name in the register of protected designations of origin and protected geographical indications (Saucisson sec d'Auvergne/Saucisse sèche d'Auvergne (PGI))**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs <sup>(1)</sup>, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, France's application to register the name 'Saucisson sec d'Auvergne'/'Saucisse sèche d'Auvergne' was published in the *Official Journal of the European Union* <sup>(2)</sup>.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Saucisson sec d'Auvergne'/'Saucisse sèche d'Auvergne' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

*Article 1*

The name 'Saucisson sec d'Auvergne'/'Saucisse sèche d'Auvergne' (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.2. Meat products (cooked, salted, smoked, etc.), as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 <sup>(3)</sup>.*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 September 2016.

*For the Commission,*  
*On behalf of the President,*  
Phil HOGAN  
*Member of the Commission*

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<sup>(1)</sup> OJ L 343, 14.12.2012, p. 1.

<sup>(2)</sup> OJ C 160, 4.5.2016, p. 14.

<sup>(3)</sup> Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

**COMMISSION REGULATION (EU) 2016/1677****of 14 September 2016****establishing a prohibition of fishing for Norway lobster in areas VIIIa, VIIIb, VIIIc and VIIE by vessels flying the flag of Belgium**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy <sup>(1)</sup>, and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) 2016/72 <sup>(2)</sup> lays down quotas for 2016.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2016.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1***Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2016 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2***Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3***Entry into force**

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

<sup>(1)</sup> OJ L 343, 22.12.2009, p. 1.

<sup>(2)</sup> Council Regulation (EU) 2016/72 of 22 January 2016 fixing for 2016 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, and amending Regulation (EU) 2015/104 (OJ L 22, 28.1.2016, p. 1).



This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 September 2016.

*For the Commission,  
On behalf of the President,  
João AGUIAR MACHADO  
Director-General for Maritime Affairs and Fisheries*

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ANNEX

No	25/TQ72
Member State	Belgium
Stock	NEP/8ABDE.
Species	Norway lobster ( <i>Nephrops Norvegicus</i> )
Zone	VIIIa, VIIIb, VIId and VIIf
Closing date	20.8.2016

**COMMISSION REGULATION (EU) 2016/1678**  
**of 14 September 2016**  
**establishing a prohibition of fishing for hake in areas VIIIa, VIIIb, VIIIc and VIIIe by vessels flying the flag of Belgium**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy <sup>(1)</sup>, and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) 2016/72 <sup>(2)</sup> lays down quotas for 2016.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2016.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2016 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2*

**Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

<sup>(1)</sup> OJ L 343, 22.12.2009, p. 1.

<sup>(2)</sup> Council Regulation (EU) 2016/72 of 22 January 2016 fixing for 2016 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, and amending Regulation (EU) 2015/104 (OJ L 22, 28.1.2016, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 September 2016.

*For the Commission,  
On behalf of the President,  
João AGUIAR MACHADO  
Director-General for Maritime Affairs and Fisheries*

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ANNEX

No	26/TQ72
Member State	Belgium
Stock	HKE/8ABDE.
Species	Hake ( <i>Merluccius merluccius</i> )
Zone	VIIIa, VIIIb, VIId and VIIE
Closing date	20.8.2016

**COMMISSION REGULATION (EU) 2016/1679****of 14 September 2016****establishing a prohibition of fishing for plaice in VIII, IX and X; Union waters of CECAF 34.1.1 by vessels flying the flag of Belgium**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy <sup>(1)</sup>, and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) 2016/72 <sup>(2)</sup> lays down quotas for 2016.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2016.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1***Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2016 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2***Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3***Entry into force**

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

<sup>(1)</sup> OJ L 343, 22.12.2009, p. 1.

<sup>(2)</sup> Council Regulation (EU) 2016/72 of 22 January 2016 fixing for 2016 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, and amending Regulation (EU) 2015/104 (OJ L 22, 28.1.2016, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 September 2016.

*For the Commission,  
On behalf of the President,  
João AGUIAR MACHADO  
Director-General for Maritime Affairs and Fisheries*

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ANNEX

No	27/TQ72
Member State	Belgium
Stock	PLE/8/3411
Species	Plaice ( <i>Pleuronectes platessa</i> )
Zone	VIII, IX and X; Union waters of CECAF 34.1.1
Closing date	20.8.2016

**COMMISSION REGULATION (EU) 2016/1680**  
**of 14 September 2016**  
**establishing a prohibition of fishing for sole in areas VIIIa and VIIIb vessels flying the flag of Belgium**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy <sup>(1)</sup>, and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) 2016/72 <sup>(2)</sup> lays down quotas for 2016.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2016.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2016 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2*

**Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

<sup>(1)</sup> OJ L 343, 22.12.2009, p. 1.

<sup>(2)</sup> Council Regulation (EU) 2016/72 of 22 January 2016 fixing for 2016 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, and amending Regulation (EU) 2015/104 (OJ L 22, 28.1.2016, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 September 2016.

*For the Commission,  
On behalf of the President,  
João AGUIAR MACHADO  
Director-General for Maritime Affairs and Fisheries*

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ANNEX

No	28/TQ72
Member State	Belgium
Stock	SOL/8AB.
Species	Common sole ( <i>Solea solea</i> )
Zone	VIIIa and VIIIb
Closing date	20.8.2016

**COMMISSION REGULATION (EU) 2016/1681****of 14 September 2016****establishing a prohibition of fishing for megrims in areas VIIIa, VIIIb, VIIIc and VIIE by vessels flying the flag of Belgium**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy <sup>(1)</sup>, and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) 2016/72 <sup>(2)</sup> lays down quotas for 2016.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2016.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1***Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2016 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2***Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3***Entry into force**

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

<sup>(1)</sup> OJ L 343, 22.12.2009, p. 1.

<sup>(2)</sup> Council Regulation (EU) 2016/72 of 22 January 2016 fixing for 2016 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, and amending Regulation (EU) 2015/104 (OJ L 22, 28.1.2016, p. 1).



This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 September 2016.

*For the Commission,  
On behalf of the President,  
João AGUIAR MACHADO  
Director-General for Maritime Affairs and Fisheries*

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ANNEX

No	29/TQ72
Member State	Belgium
Stock	LEZ/*8ABDE
Species	Megrimms ( <i>Lepidorhombus</i> spp.)
Zone	VIIIa, VIIIb, VIId and VIIf
Closing date	20.8.2016

**COMMISSION REGULATION (EU) 2016/1682****of 14 September 2016****establishing a prohibition of fishing for anglerfish in areas VIIIa, VIIIb, VIIIc and VIIIe by vessels flying the flag of Belgium**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy <sup>(1)</sup>, and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) 2016/72 <sup>(2)</sup> lays down quotas for 2016.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2016.
- (3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

*Article 1***Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2016 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2***Prohibitions**

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3***Entry into force**

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

<sup>(1)</sup> OJ L 343, 22.12.2009, p. 1.

<sup>(2)</sup> Council Regulation (EU) 2016/72 of 22 January 2016 fixing for 2016 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, and amending Regulation (EU) 2015/104 (OJ L 22, 28.1.2016, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 September 2016.

*For the Commission,  
On behalf of the President,  
João AGUIAR MACHADO  
Director-General for Maritime Affairs and Fisheries*

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ANNEX

No	30/TQ72
Member State	Belgium
Stock	ANF/*8ABDE
Species	Anglerfish ( <i>Lophiidae</i> )
Zone	VIIIa, VIIIb, VIId and VIIE
Closing date	20.8.2016

**COMMISSION IMPLEMENTING REGULATION (EU) 2016/1683****of 19 September 2016****amending for the 253rd time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaeda organisations**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaeda organisations <sup>(1)</sup>, and in particular Article 7(1)(a) and Article 7a(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.
- (2) On 14 September 2016, the Sanctions Committee of the United Nations Security Council decided to amend two entries in its list of persons, groups and entities to whom the freezing of funds and economic resources should apply. Annex I to Regulation (EC) No 881/2002 should therefore be updated accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EC) No 881/2002 is amended in accordance with the Annex to this Regulation.

*Article 2*This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 September 2016.

*For the Commission,  
On behalf of the President,  
Acting Head of the Service for Foreign Policy Instruments*

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<sup>(1)</sup> OJ L 139, 29.5.2002, p. 9.

## ANNEX

The following entries under the heading 'Natural persons' in Annex I to Regulation (EC) No 881/2002 are amended as follows:

- (a) 'Ali Ben Taher Ben Faleh Ouni Harzi (alias: Abou Zoubair). Date of birth: 9.3.1986. Place of birth: Ariana, Tunisia. Nationality: Tunisian. Passport No: W342058 (Tunisian passport, issued on 14.3.2011, expires on 13.3.2016). National identification No: 08705184 (Tunisian National Identity Card number, issued on 24.2.2011). Address: (a) 18 Mediterranean Street, Ariana, Tunisia; (b) Syrian Arab Republic (located in as at Mar. 2015); (c) Iraq (possible alternative location as at Mar. 2015); (d) Libya (previously located in). Other information: (a) Physical description: eye colour: brown; height: 171 cm; (b) Photo available for inclusion in the Interpol-UN Security Council Special Notice; (c) Father's name is Taher Ouni Harzi, mother's name is Borkana Bedairia. Date of designation referred to in Article 2a(4)(b): 10.4.2015' is replaced by the following:

'Ali Ben Taher Ben Faleh Ouni Harzi (alias: Abou Zoubair). Date of birth: 9.3.1986. Place of birth: Ariana, Tunisia. Nationality: Tunisian. Passport No: W342058 (Tunisian passport, issued on 14.3.2011, expires on 13.3.2016). National identification No: 08705184 (Tunisian National Identity Card number, issued on 24.2.2011). Address: (a) 18 Mediterranean Street, Ariana, Tunisia; (b) Syrian Arab Republic (located in as at Mar. 2015); (c) Iraq (possible alternative location as at Mar. 2015); (d) Libya (previously located in). Other information: (a) Physical description: eye colour: brown; height: 171 cm; (b) Photo available for inclusion in the Interpol-UN Security Council Special Notice; (c) Father's name is Taher Ouni Harzi, mother's name is Borkana Bedairia. Reportedly killed in an airstrike in Mosul, Iraq, in Jun. 2015. Date of designation referred to in Article 7d(2)(i): 10.4.2015.'

- (b) 'Tarak Ben Taher Ben Faleh Ouni Harzi (alias: Abou Omar Al Tounisi). Date of birth: 3.5.1982. Place of birth: Tunis, Tunisia. Nationality: Tunisian. Passport No: Z050399 (Tunisian passport, issued on 9.12.2003, expired on 8.12.2008). National identification No: 04711809 (Tunisian National Identity Card number, issued on 13.11.2003). Address: (a) 18 Mediterranean Street, Ariana, Tunisia; (b) Syrian Arab Republic (located in as at March 2015); (c) Iraq (possible alternative location as at March 2015); (d) Libya (previously located in). Other information: (a) Physical description: eye colour: brown; height: 172 cm; (b) Photo available for inclusion in the Interpol-UN Security Council Special Notice; (c) Father's name is Taher Ouni Harzi, mother's name is Borkana Bedairia. Date of designation referred to in Article 2a(4)(b): 10.4.2015' is replaced by the following:

'Tarak Ben Taher Ben Faleh Ouni Harzi (alias: Abou Omar Al Tounisi). Date of birth: 3.5.1982. Place of birth: Tunis, Tunisia. Nationality: Tunisian. Passport No: Z050399 (Tunisian passport, issued on 9.12.2003, expired on 8.12.2008). National identification No: 04711809 (Tunisian National Identity Card number, issued on 13.11.2003). Address: (a) 18 Mediterranean Street, Ariana, Tunisia; (b) Syrian Arab Republic (located in as at March 2015); (c) Iraq (possible alternative location as at March 2015); (d) Libya (previously located in). Other information: (a) Physical description: eye colour: brown; height: 172 cm; (b) Photo available for inclusion in the Interpol-UN Security Council Special Notice; (c) Father's name is Taher Ouni Harzi, mother's name is Borkana Bedairia. Reportedly killed in Syria in Jun. 2015. Date of designation referred to in Article 7d(2)(i): 10.4.2015.'

**COMMISSION IMPLEMENTING REGULATION (EU) 2016/1684****of 19 September 2016****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 <sup>(1)</sup>,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors <sup>(2)</sup>, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.
- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

*Article 1*

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 September 2016.

*For the Commission,  
On behalf of the President,  
Jerzy PLEWA*

*Director-General for Agriculture and Rural Development*

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<sup>(1)</sup> OJ L 347, 20.12.2013, p. 671.

<sup>(2)</sup> OJ L 157, 15.6.2011, p. 1.

## ANNEX

## Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)			
CN code	Third country code <sup>(1)</sup>	Standard import value	
0702 00 00	MA	180,4	
	ZZ	180,4	
0707 00 05	TR	116,3	
	ZZ	116,3	
0709 93 10	TR	136,2	
	ZZ	136,2	
0805 50 10	AR	105,8	
	CL	129,5	
	MA	81,7	
	TR	132,7	
	UY	87,3	
	ZA	119,5	
	ZZ	109,4	
	0806 10 10	EG	265,2
		TR	132,3
		ZZ	198,8
0808 10 80	AR	181,9	
	BR	97,9	
	CL	134,5	
	NZ	124,1	
	US	141,5	
	ZA	101,2	
	ZZ	130,2	
	0808 30 90	AR	168,5
CL		101,2	
TR		135,7	
ZA		126,0	
ZZ		132,9	
0809 30 10, 0809 30 90	TR	134,2	
	ZZ	134,2	

<sup>(1)</sup> Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2016/1685

of 16 September 2016

**authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maizes combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU**

*(notified under document C(2016) 5746)*

**(Only the French text is authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Articles 7(3), 9(2), 19(3) and 21(2) thereof,

Whereas:

- (1) On 9 February 2009, Syngenta France SAS submitted to the competent authority of Germany an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from Bt11 × MIR162 × MIR604 × GA21 maize ('the application').
- (2) The application also covers the placing on the market of genetically modified maize Bt11 × MIR162 × MIR604 × GA21 in products consisting of it or containing it for other uses than food and feed as any other maize, with the exception of cultivation.
- (3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council <sup>(2)</sup> and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to that Directive. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (4) On 5 July 2013, Syngenta extended the scope of the application to all sub-combinations of the single genetic modification events constituting Bt11 × MIR162 × MIR604 × GA21 maize ('sub-combinations'), including Bt11 × GA21 maize, MIR604 × GA21 maize, Bt11 × MIR604 maize, and Bt11 × MIR604 × GA21 which are already authorised respectively by Commission Decisions 2010/426/EU <sup>(3)</sup>, 2011/892/EU <sup>(4)</sup>, 2011/893/EU <sup>(5)</sup> and 2011/894/EU <sup>(6)</sup>. Syngenta asked the Commission to repeal those four Decisions once authorisation is given to Bt11 × MIR162 × MIR604 × GA21 maize and all sub-combinations.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

<sup>(3)</sup> Commission Decision 2010/426/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × GA21 (SYN-BTØ11-1 × MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 199, 31.7.2010, p. 36).

<sup>(4)</sup> Commission Decision 2011/892/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604 × GA21 (SYN-IR6Ø4-5 × MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 55).

<sup>(5)</sup> Commission Decision 2011/893/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR604 (SYN-BTØ11-1 × SYN-IR6Ø4-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 59).

<sup>(6)</sup> Commission Decision 2011/894/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR604 × GA21 (SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 64).



- (5) On 7 December 2015, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 <sup>(1)</sup>. It concluded that genetically modified maize Bt11 × MIR162 × MIR604 × GA21, as described in the application, is as safe and as nutritious as its conventional counterpart and no safety concerns are identified for any of the sub-combinations.
- (6) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (7) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (8) In its opinion, EFSA recommends the collection of relevant information on expression levels of the newly expressed proteins, if the sub-combinations Bt11 × MIR162 × MIR604, MIR162 × MIR604 × GA21, Bt11 × MIR162, MIR162 × MIR604 and/or MIR162 × GA21 were to be created via targeted breeding approaches and commercialised. In line with this recommendation, specific conditions should be laid down to that effect.
- (9) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, Bt11 × MIR162 × MIR604, Bt11 × MIR162 × GA21, Bt11 × MIR604 × GA21, MIR162 × MIR604 × GA21, Bt11 × MIR162, Bt11 × MIR604, Bt11 × GA21, MIR162 × MIR604, MIR162 × GA21 and MIR604 × GA21.
- (10) Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU authorising Bt11 × GA21 maize, MIR604 × GA21 maize, Bt11 × MIR604 maize, and Bt11 × GA21 × MIR604 maize should be repealed.
- (11) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 <sup>(2)</sup>.
- (12) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21 including all possible combinations of the single genetic modification events. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of maize Bt11 × MIR162 × MIR604 × GA21 and the sub-combinations, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.
- (13) Regulation (EC) No 1830/2003 of the European Parliament and of the Council <sup>(3)</sup> lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for those products are laid down in paragraphs 1 to 5 of Article 4 and traceability requirements for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (14) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC <sup>(4)</sup>. The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

<sup>(1)</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Scientific Opinion on an application by Syngenta (EFSA-GMO-DE-2009-66) for placing on the market of herbicide tolerant and insect resistant maize Bt11 × MIR162 × MIR604 × GA21 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2015;13(12):4297, 34 pp. doi:10.2903/j.efsa.2015.4297

<sup>(2)</sup> Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

<sup>(3)</sup> Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

<sup>(4)</sup> Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

- (15) The authorisation holder should also submit annual reports on the results of the activities set out in the specific conditions of this authorisation.
- (16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed provided for in Regulation (EC) No 1829/2003.
- (17) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council <sup>(1)</sup>.
- (18) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

#### Article 1

#### Genetically modified organism and unique identifier

1. The following unique identifiers for genetically modified organisms (GMOs) are assigned in accordance with Regulation (EC) No 65/2004:

- (a) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × MIR604 × GA21;
- (b) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × MIR604;
- (c) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × GA21;
- (d) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604 × GA21;
- (e) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR162 × MIR604 × GA21;
- (f) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162;
- (g) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604;
- (h) the unique identifier SYN-BTØ11-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × GA21;
- (i) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) MIR162 × MIR604;
- (j) the unique identifier SYN-IR162-4 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR162 × GA21;
- (k) the unique identifier SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR604 × GA21.

2. The genetically modified maizes referred to in paragraph 1 are specified in point (b) of the Annex.

<sup>(1)</sup> Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2***Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from the GMOs referred to in Article 1;
- (b) feed containing, consisting of, or produced from the GMOs referred to in Article 1;
- (c) GMOs referred to in Article 1 in products containing them or consisting of them for any other use than those provided in points (a) and (b), with the exception of cultivation.

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of the GMOs referred to in Article 1, with the exception of products referred to in point (a) of Article 2.

*Article 4***Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5***Specific conditions for the placing on the market**

1. The authorisation holder shall ensure that the specific conditions, referred to in point (g) of the Annex, are implemented.
2. The authorisation holder shall submit to the Commission annual reports on the results of the activities set out in the specific conditions of this authorisation for the duration of the authorisation.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Syngenta France SAS, representing Syngenta Crop Protection AG, Switzerland.

*Article 8***Repeal**

Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU are repealed.

*Article 9***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 10***Addressee**

This Decision is addressed to Syngenta France SAS, 12, Chemin de l'Hobit, 31790 Saint-Sauveur, France.

Done at Brussels, 16 September 2016.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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## ANNEX

**(a) Applicant and Authorisation holder:**

Name: Syngenta France SAS

Address: 12, Chemin de l'Hobit, 31790 Saint-Sauveur, France

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, CHH-4058 Basel, Switzerland.

**(b) Designation and specification of the products:**

- (1) foods and food ingredients containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);
- (2) feed containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);
- (3) genetically modified maizes (*Zea mays* L.) as specified in (e) in products containing them or consisting of them for any other use than those provided in points (1) and (2), with the exception of cultivation.

SYN-BTØ11-1 maize expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and a PAT protein which confers tolerance to glufosinate-ammonium herbicides.

SYN-IR162-4 maize expresses the Vip3Aa20 protein which confers protection against certain lepidopteran pests and PMI protein which was used as a selectable marker.

SYN-IR6Ø4-5 maize expresses the Cry3A protein which provides protection against certain coleopteran pests and PMI protein which was used as a selectable marker.

MON-ØØØ21-9 maize expresses the mEPSPS protein which confers tolerance to glyphosate herbicides.

**(c) Labelling:**

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting the maizes specified in (e) with the exception of products referred to in point (a) of Article 2.

**(d) Method for detection:**

- (1) Event specific real-time quantitative PCR based methods for SYN-BTØ11-1, SYN-IR162-4, SYN-IR6Ø4-5 and MON-ØØØ21-9 maizes; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9 maize;
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;
- (3) Reference Material: ERM®-BF412 (for SYN-BTØ11-1) and ERM®-BF423 (for SYN-IR6Ø4-5) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://irmm.jrc.ec.europa.eu/rmcatalogue> and AOCs 1208-A and AOCs 0407-A (for SYN-IR162-4), AOCs 0407-A and AOCs 0407-B (for MON-ØØØ21-9) accessible via the American Oil Chemists Society at <http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248>.

**(e) Unique identifier:**

SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5;

SYN-BTØ11-1 × SYN-IR162-4 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-ØØØ21-9;

SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR162-4;

SYN-BTØ11-1 × SYN-IR6Ø4-5;

SYN-BTØ11-1 × MON-ØØØ21-9;

SYN-IR162-4 × SYN-IR6Ø4-5;

SYN-IR162-4 × MON-ØØØ21-9;

SYN-IR6Ø4-5 × MON-ØØØ21-9.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

*Specific conditions in accordance with Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003:*

(1) The authorisation holder shall inform the Commission if the sub-combinations SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5, SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9, SYN-BTØ11-1 × SYN-IR162-4, SYN-IR162-4 × SYN-IR6Ø4-5 and/or SYN-IR162-4 × MON-ØØØ21-9 were to be created via targeted breeding approaches and commercialised.

(2) If it is the case, the authorisation holder shall collate information on the expression levels of the newly expressed proteins.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

*Note:* links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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